OCT 1 9 2001

K013356
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RE: SPECIAL 510(K): DEVICE MODIFICATION FOR THE WILSON-COOK ULTRASOUND BIOPSY NEEDLE

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitted By:
Wilson-Cook Medical Inc.
4900 Bethania Station Road
& 5951 Grassy Creek Boulevard
Winston-Salem, NC 27105

Device Description:
The Wilson-Cook Modified Ultrasound Biopsy Needle is used for soft tissue biopsy through the accessory channel of an ultrasound endoscope. This device is supplied sterile and intended for single use only.

Trade Name:	Wilson-Cook Ultrasound Biopsy Needle
Common/Usual Name:	Ultrasound Biopsy Needle
Classification Name/Code:	Set, Biopsy Needle and Needle, GU, 78 FCG
Classification:	FDA has classified similar devices as Class II, as per 21 CFR § 876.1075. This device falls within the purview of the Gastroenterology and Urology Device Panel.
Performance Standards:	To the best of our knowledge, performance standards for this device do not exist.
Intended Use:	Used for soft tissue biopsy through the accessory channel of an ultrasound endoscope.

Predicate Device:

PREDICATE DEVICE	MANUFACTURER	DOCUMENT CONTROL NUMBER
ProAct Biopsy Needle	ProAct Ltd.	K926559/A
Wilson-Cook Ultrasound Needle	Wilson-Cook Medical Inc.	K934356

Substantial Equivalence:
The Wilson-Cook Modified Ultrasound Biopsy Needle is substantially equivalent to the referenced predicate devices with respect to design, materials of construction and intended use.

This device is identical to the ProAct Biopsy Needle in the side-cutting configuration of the needle, as well as the echogenic needle tip. In addition, both of these devices operate in the same manner in order to obtain biopsies.

The modified Ultrasound Biopsy Needle and the predicate Wilson-Cook Ultrasound Needle are both used endoscopically, employing ultrasound technology to guide the needle. The patient-contacting materials of these devices differ slightly, with the sheath of the predicate being polytetrafluoroethylene and the sheath of the modified device being PEEK. In addition, the stylet of the predicate is comprised of ANSI Grade 304 Stainless Steel while the modified device stylet is comprised of Titanium Nickel (Nitinol). Applicable biocompatibility data is included.

RE: SPECIAL 510(K): DEVICE MODIFICATION FOR THE WILSON-COOK ULTRASOUND BIOPSY NEEDLE

I. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS (continued)

DEVICE CHARACTERISTIC	Wilson-Cook Modified Ultrasound Biopsy Needle [Subject of Special 510(k)]	ProAct Biopsy Needle (K926559/A)	Predicate Wilson-Cook Ultrasound Needle (K934356)
Intended Use	Used for soft tissue biopsy through the accessory channel of an ultrasound endoscope.	Used for percutaneous, intra-operative, or through a laparoscope biopsies.	Used for aspiration biopsy to diagnose and stage GI lesions, providing sampling by employing ultrasound technology to guide the needle.
Sterility	Sterile, Disposable	Sterile, Disposable	Sterile, Disposable

Biocompatibility:

Reasonable assurance of biocompatibility for the patient-contacting materials has been established through a history of use in similar patient-contacting medical devices and as applicable biocompatibility test results.

Design Control/Risk Analysis/Design Verification:

Design Control, Risk Analysis, Design Verification activities for the subject of this special 510(k) have been conducted in accordance with all applicable internal procedures. The design control process employed is inclusive of the elements as stipulated by 21 CFR Part 820.30, as applicable to the project. The risk analysis performed identified the risks relative to the performance requirements, as specified by our internal procedure for Risk Analysis. The failure mode, effect of failure, severity, potential cause, rate of occurrence, design control element/production controls to eliminate, the potential to detect and our recommended actions were also documented. During Design Verification, dimensional and functional testing to ensure the performance and design integrity of this product line were conducted. All results obtained during our Design Verification met our predetermined acceptance criteria for this product line.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 9 2001

Ms. Margaret J. Posner
Regulatory Affairs Specialist
Wilson-Cook Medical
GI Endoscopy
4900 Bethania Station Road
WINSTON-SALAM NC 27105

Re: K013356
Trade/Device Name: Wilson-Cook Ultrasound Biopsy Needle
Regulation Number: 21 CFR 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: 78 FCG
Dated: September 28, 2001
Received: October 10, 2001

Dear Ms. Posner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K013356

Device Name: Wilson-Cook Ultrasound Biopsy Needle

Indications for Use:

Used for soft tissue biopsy through the accessory channel of an ultrasound endoscope.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE, IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter _____
(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013356